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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,877	02/08/2002	Robert C. Downs	36-001810US	9765
22798	7590	12/29/2004		
QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501				
			EXAMINER SINES, BRIAN J	
			ART UNIT 1743	PAPER NUMBER

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/071,877	<b>Applicant(s)</b> DOWNS ET AL.	
	<b>Examiner</b> Brian J. Sines	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-113 is/are pending in the application.
- 4a) Of the above claim(s) 59-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20, 24-44, 48, 56, 58 and 85-113 is/are rejected.
- 7) ☒ Claim(s) 21-23, 45-47, 49-55 and 57 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of group I comprising claims 1 – 58 and 85 – 113 in the response filed 1/20/2004 is acknowledged. Claims 59 – 84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

This application contains claims 59 – 84 drawn to an invention nonelected without traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

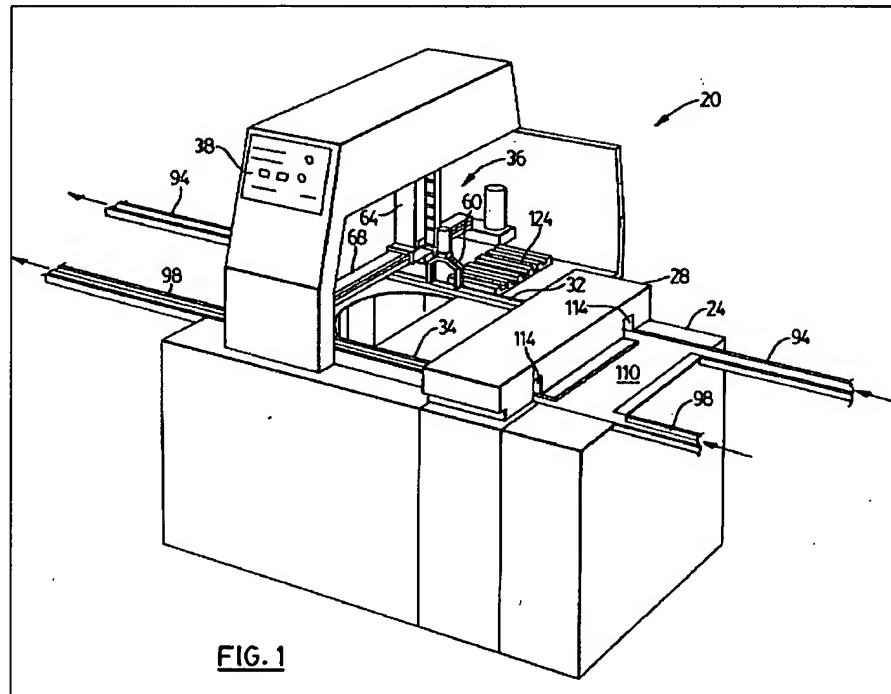
A person shall be entitled to a patent unless –

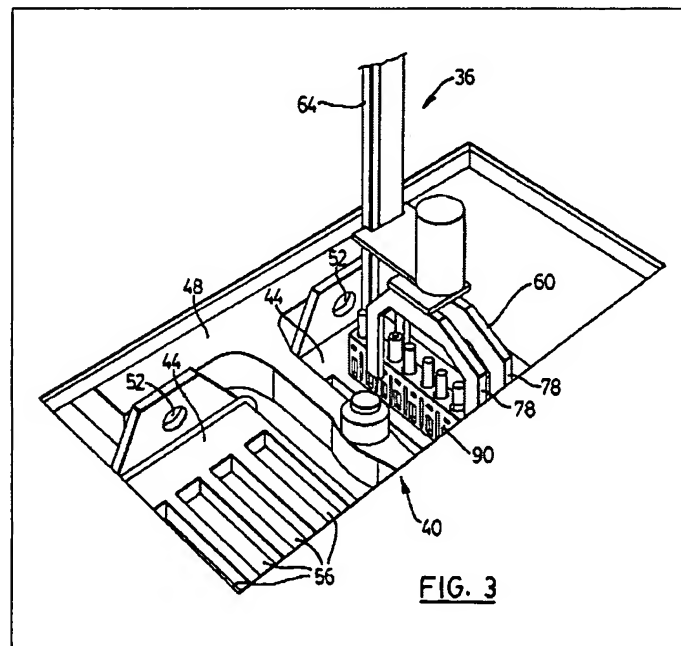
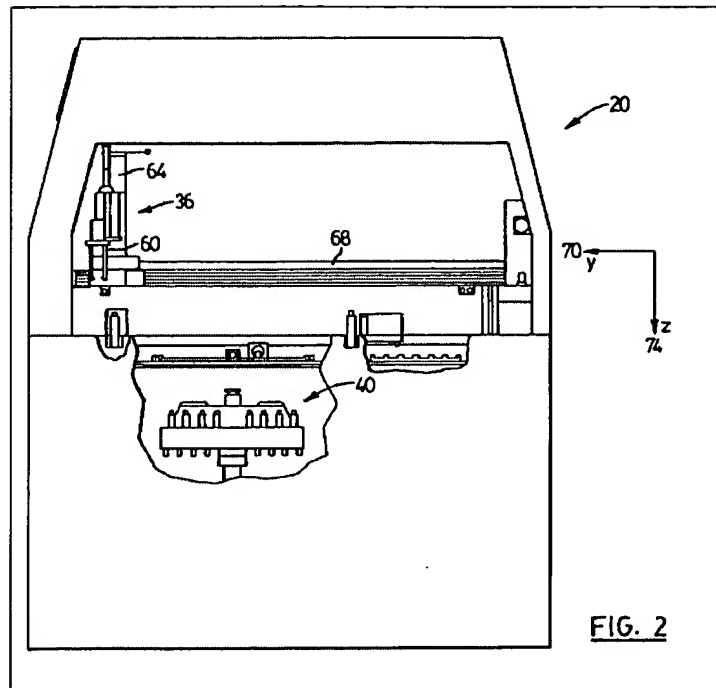
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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1. Claims 1, 4 – 20, 24 – 40, 48, 56 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Quinlan et al. (U.S. Pat. No. 5,769,775 A). Quinlan et al. teach an automated centrifuge apparatus comprising: a rotor (40) comprising a plurality of sample receiving regions (44 & 56); and a transport mechanism (e.g., 24, 36, 60, 64, 78, 94, 98) configured to move one or more sample processing components (e.g., rack 90) proximal to or within the plurality of sample receiving regions (see col. 3, lines 15 – 67; col. 4, lines 1 – 65; figures 1 – 3).

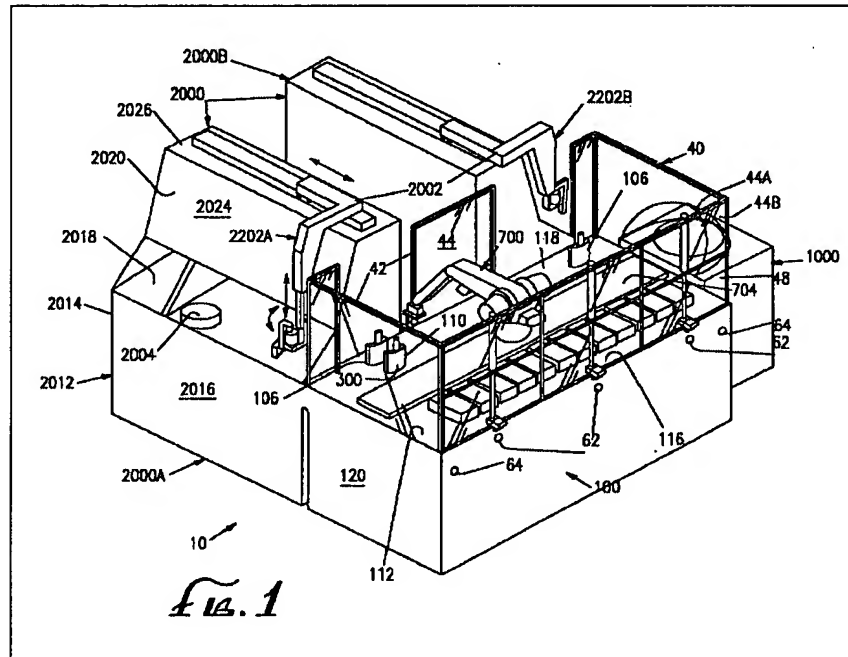




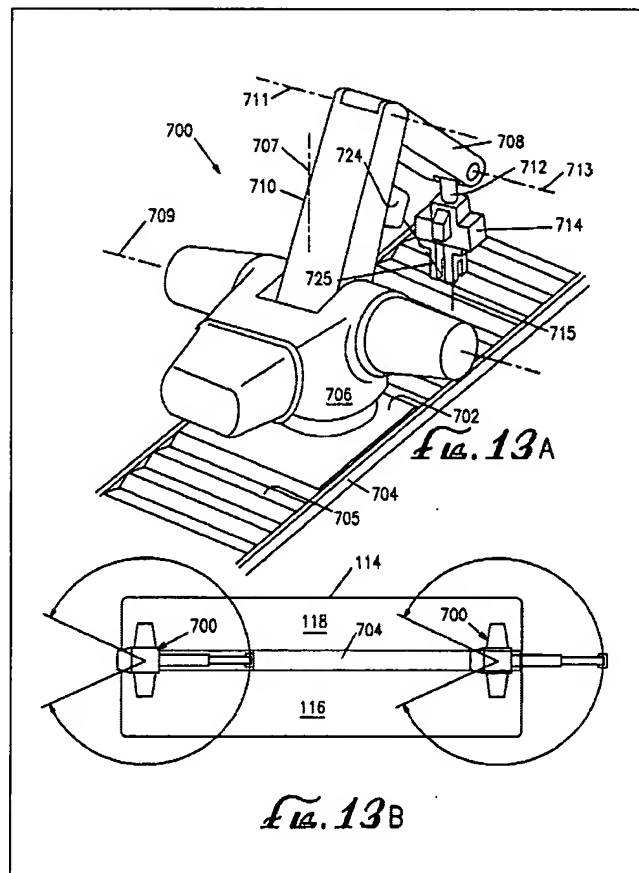
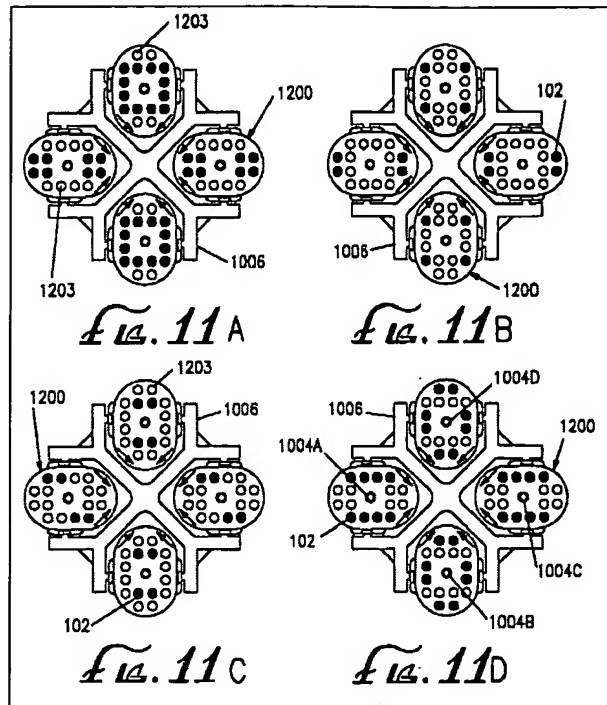
2. Claims 1 – 20, 24 – 44 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Pang et al. (U.S. Pat. No. 6,060,022 A). Pang et al. teach an automated centrifuge apparatus comprising: a centrifuge rotor (1000) comprising a plurality of sample receiving regions (receptacles 1200); and a transport mechanism (robotic arms

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700 & 2002) configured to move one or more sample processing components (e.g., each rack 600 comprises a holder 14 for containers 12 or 120) proximal to or within the plurality of sample receiving regions (see col. 1, line 1 – col. 14, line 64; col. 20, lines 6 – 61; col. 21, lines 4 – 61; col. 27, lines 8 – 67; figures 1 – 21). The apparatus includes an optical position sensor and an indicia scanner (see col. 8, lines 1 – 32). The apparatus comprises two analyzers for selectively performing at least two different analyses on a specimen (see col. 6, lines 51 – 67).



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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 85 – 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quinlan et al. in view of Lewis et al. (U.S. Pat. No. 5,024,646). Regarding claims 85 – 90, 92 – 95 and 97, Quinlan et al. teach an automated centrifuge apparatus for biological sample analysis comprising: a rotor (40) comprising a plurality of clusters comprising sample receiving elements (rack trays 44); and a transport mechanism (e.g., 24, 36, 60, 64, 78, 94, 98) configured to move one or more sample processing components (e.g., rack 90) (see col. 3, lines 15 – 67; col. 4, lines 1 – 65; figures 1 – 3). Quinlan et al. do not specifically teach that the clusters are non-vertical. Lewis et al. teach a fixed-angle or non-vertical centrifuge system (see col. 3, lines 31 – 51; figure 5). Lewis et al. do teach the advantages of using a non-vertical centrifuge system for density gradient separations in analyzing biological samples (see col. 3, lines 13 – 51). Hence, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in using a



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non-vertical centrifuge system in performing biological sample analysis, as taught by Lewis et al. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a non-vertical centrifuge system, as taught by Lewis et al., with the apparatus of Quinlan et al. in order to perform the recited method.

Regarding the methodology recited in the instant claims, as discussed above, Quinlan et al. in view of Lewis et al. teaches all of the structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Regarding process or method claims, a prior art device anticipates a claimed process, if the device carries out the process during normal operation (see MPEP § 2112.02). Furthermore, regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01). Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method recited in the instant claims upon the apparatus of Quinlan et al. in view of Lewis et al., as such is the intended operation of that apparatus.

2. Claims 85 – 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pang et al. in view of Lewis et al. (U.S. Pat. No. 5,024,646). Pang et al. teach an automated centrifuge apparatus comprising: a centrifuge rotor (1000) comprising a plurality of sample receiving regions (receptacles 1200); and a transport mechanism (robotic arms 700 & 2002) configured to move one or more sample processing

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components (e.g., each rack 600 comprises a holder 14 for containers 12 or 120) proximal to or within the plurality of sample receiving regions (see col. 1, line 1 – col. 14, line 64; col. 20, lines 6 – 61; col. 21, lines 4 – 61; col. 27, lines 8 – 67; figures 1 – 21). The apparatus includes an optical position sensor and an indicia scanner (see col. 8, lines 1 – 32). The apparatus comprises two analyzers for selectively performing at least two different analyses on a specimen (see col. 6, lines 51 – 67). Pang et al. do not specifically teach that the clusters are non-vertical. Lewis et al. teach a fixed-angle or non-vertical centrifuge system (see col. 3, lines 31 – 51; figure 5). Lewis et al. do teach the advantages of using a non-vertical centrifuge system for density gradient separations in analyzing biological samples (see col. 3, lines 13 – 51). Hence, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in using a non-vertical centrifuge system in performing biological sample analysis, as taught by Lewis et al. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a non-vertical centrifuge system, as taught by Lewis et al., with the apparatus of Pang et al. in order to perform the recited method.

Regarding the methodology recited in the instant claims, as discussed above, Pang et al. in view of Lewis et al. teaches all of the structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Regarding process or method claims, a prior art device anticipates a claimed process, if the device carries out the process during normal operation (see MPEP § 2112.02).

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Furthermore, regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01). Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method recited in the instant claims upon the apparatus of Pang et al. in view of Lewis et al., as such is the intended operation of that apparatus.

#### ***Allowable Subject Matter***

Claims 21 – 23, 45 – 47, 49 – 55 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The cited prior art neither teach or fairly suggest the further incorporation of the claim limitations recited by claims 21 – 23, 45 – 47, 49 – 55 and 57 within the apparatus of either Quinlan et al. or Pang et al.

#### ***Response to Arguments***

1. The objection of the drawings under 37 CFR 1.83(a) has been withdrawn.
2. Applicant's arguments with respect to claims 1, 4 – 20, 24 – 40, 48, 56, 58 and 85 – 113 under 35 U.S.C. 102(b) as being anticipated by Quinlan et al. (U.S. Pat. No. 5,769,775 A) have been considered, but are moot in view of the new ground(s) of rejection.
3. Applicant's arguments with respect to claims 1 – 20, 24 – 44, 48 and 85 – 113 under 35 U.S.C. 102(e) as being anticipated by Pang et al. (U.S. Pat. No. 6,060,022 A) have been considered, but are moot in view of the new ground(s) of rejection. .

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***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Reeves and Wright et al. teach fixed-angle or non-vertical rotor centrifuge systems.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).